

### **REMARKS**

Claims 1-21 and 26-47 are pending in the instant application. Claims 1-21 and 26-47 have been rejected by the Examiner. The rejections have been made final by the Examiner.

By the above amendments, Claims 1, 6, 26 and 31 have been amended to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More particularly, Claims 1 and 26 have been amended to more particularly point out that Step (A) and Step (B) are run in a continuous manner. Further, Claims 1 and 26 have been amended to limit the first organic solvent to a solvent selected from a cyclic ether, or a straight or branched chain dialkyl ether and further limit the second organic solvent to be the same as the first organic solvent. Claims 6 and 31 have been amended to recite that the first organic solvent and the second organic solvent are each glyme. Applicants submit that the amendments are fully supported by the specification as filed, and no new matter is being added (see for example, page 9, lines 10-15 of the specification). By the above amendments Claims 4, 5, 11, 29, 30 and 36 have been canceled without prejudice. After entry of the amendments, Claims 1-3, 6-10, 12-21, 26-28, 31-35 and 37-47 will remain pending and under consideration.

Reconsideration of the captioned application based on the previous amendments and following remarks is respectfully requested.

In the final rejection of Claim 1-21 and 26-47, the Examiner provides the following reasoning for maintaining the rejections under 35 U.S.C. §103(a) in view of Maryanoff et al., US Patent 5,387,700, which discloses a process for the preparation of fructopyranose sulfamate derivatives of formula (I) and topiramate. The Examiner states:

It is clear from the art that ethers and hydrocarbons can be used as solvents in the instant 2-step process. It is also clear that use of the same ether solvent for each of the steps is contemplated. See the reference at col. 3, lines 10-20. Applicants have amended claim 1 to remove tetrahydrofuran and t-butyl methyl ether the solvents specifically disclosed by the reference. However use of another cyclic ether or

straight or branched chain dialkyl ether as solvent in both steps would have been manifestly obvious to the ordinarily skilled worker in the art.

The process described by applicants in the specification is not "continuous in the sense that after the first reaction is completed, the second is run without intermediate steps. Note that the reaction mixture is filtered and then some of the solvent is evaporated before the second step is run.

Applicants have not shown that by using glyme as the solvent in both steps that a process giving unexpectedly improved results occurs.

. . . The actual process taught by Maryanoff is as "continuous" as that performed by applicants. Note for example that both concentrate the reaction mixture obtained from the first reaction step.

Applicants respectfully traverse the rejection. Applicants submit that the Examiner has maintained two grounds for the final rejection under 35 U.S.C. §103(a), the first related to the solvent used in the two steps of the process(es) of the present invention and the second related to the continuous manner in which the process(es) of the present invention are run. Applicants will address each of these rejections separately below.

The Examiner has maintained the rejection of Claims 1-21 and 26-47 alleging that Maryanoff et al. suggest the use of any ether or hydrocarbon solvent and the use of the same solvent in the two steps of the process of the present invention.

Applicants respectfully traverse the rejection. Applicants maintain that Maryanoff et al. do not teach or suggest the process of the present invention wherein Step (A) is completed in a first organic solvent and Step (B) is completed in a second organic solvent which is the same as the first organic solvent of Step (A); and wherein neither the first organic solvent nor the second organic solvent are methyl t-butyl ether (MTBE) or tetrahydrofuran (THF).

Maryanoff et al., in US Patent 5,387,700, teach reacting an alcohol of formula  $RCH_2OH$  with sulfuryl chloride in the presence of a base, in a solvent selected from the group consisting of toluene, t-butyl methyl ether or tetrahydrofuran to yield the

compound of formula  $\text{RCH}_2\text{SO}_2\text{Cl}$ ; and then reacting the compound of formula  $\text{RCH}_2\text{SO}_2\text{Cl}$  with an amine in a solvent selected from the group consisting of tetrahydrofuran, t-butyl methyl ether and lower alkanol (e.g. methanol or ethanol). Maryanoff et al. do not teach or suggest that the reaction steps may be run in any ether or hydrocarbon (i.e. any member of the class of solvents known as ethers or hydrocarbons), but rather Maryanoff et al. call out specific examples of suitable solvents. Further, Maryanoff et al., in the Examples and specification, suggest that the preferred solvent of the first step is toluene (a hydrocarbon) and the preferred solvent of the second step is tetrahydrofuran (a cyclic ether). Thus, Maryanoff et al. suggest that the preferred solvent for the first and second steps are different (see, e.g., column 2, line 55 through column 3, line 25), and neither of these solvents preferred by Maryanoff et al. are encompassed within the instant claims, as amended.

Applicants therefore submit that the teachings of Maryanoff et al. would not motivate one skilled in the art to run the two-step process of the present invention in a manner wherein Step (A) is completed in a first organic solvent and Step (B) is completed in a second organic solvent which is the same as the first organic solvent of Step (A) and wherein neither the first organic solvent nor the second organic solvent are THF or MTBE.

The Examiner has further maintained the rejection of Claims 1-21 and 26-47 alleging that Maryanoff et al. suggest the continuous process of the present invention.

Applicants respectfully traverse the rejection. Applicants submit that Maryanoff et al. teach a process for the preparation of fructopyranose sulfamate derivatives of formula (I) and topiramate, however, the process taught by Maryanoff et al. is a batch process.

Applicants submit that a continuous process is one wherein the reactant(s) are introduced and the product(s) withdrawn in an uninterrupted manner (except for interruptions related to start-up, maintenance, or for scheduled shut down periods). By contrast, a batch process is one where all the reactants are added to the reactor and

then processed according to a predetermined course of reaction during which no material is fed into or removed from the reactor.

Applicants maintain that the process(es) of the present invention are continuous. Applicants further respectfully refer the Examiner to the above amendments of independent Claims 1 and 26 which are being submitted to more particularly point out and distinctly claim what is meant by the term "continuous" by specifically calling out that Step (A) and Step (B) are each run in a continuous manner.

The Examiner further states that the process described by Applicants in the specification is not continuous because the reaction mixture of Step (A) is filtered and some of the solvent is evaporated prior to Step (B). Applicants maintain that the process of the present claims does not require filtering the reaction mixture of Step (A), or the evaporation of a portion of the product mixture of Step (A) prior to Step (B). Applicants submit that the Examiner is erroneously importing limitations from preferred embodiment into the claims. Applicants maintain that although it may be preferred to isolate, filter and / or evaporate solvent from the product mixture of Step (A), these steps are not required by the process of the independent claims of the present invention and that such limitations are only included in dependent claims 19-20 and 44-45.

Further, Applicants submit that the isolation, filtration and evaporation of solvent of the product mixture of Step (A) prior to Step (B) does not preclude running Steps (A) and (B) in a continuous manner as in the present claims. Additionally, Applicants submit that as recited in dependent Claims 19-20 and 44-45, the step of concentrating the solution comprising the compound of formula (V) and the first organic solvent may be run in a continuous manner using technology known to one skilled in the art, for example as disclosed in the specification on page 16, lines 14-19. Thus, Applicants maintain that the process(es) of the present invention are continuous and are not obvious in view of the teachings of Maryanoff et al.

Finally, Applicants submit that although it may be desirable to convert a batch process into a continuous process, it does not necessarily and inevitably follow that a two-step batch process can be run in a continuous manner without requiring a change in solvent system (i.e. wherein each step is run in the same solvent). Further it does not necessarily and inevitably follow that the batch conditions (e.g. concentrations, amounts, temperatures, etc.) when applied to a continuous process would result in a commercially feasible process.

Applicants submit that, at most, the teaching in Maryanoff et al, US Patent 5,387,700, might make it obvious to try to run the 2-step process disclosed therein in a continuous manner and in the disclosed solvents. However, obvious to try is an improper basis for a § 103(a) rejection when there is no suggestion or expressed expectation of success in the prior art that would have led one to perform the experimentation in the first place. Although obviousness does not require absolute predictability, a reasonable expectation of success is necessary. *In re Tomlinson, Hall and Geigle*, 363 F.2d 928, 150 U.S.P.Q. 623 (C.C.P.A. 1966); *In re Clinton et al.*, 527 F.2d 1226, 188 U.S.P.Q. 365 (C.C.P.A. 1976). Applicants urge that in the instant case, there was no reasonable expectation of success that the 2-step process disclosed in Maryanoff et al. could be run in a continuous manner.

Applicants therefore maintain that one skilled in the art, in reading Maryanoff et al., US Patent 5,387,700, would not be motivated to run the two-step process of the present invention in a continuous manner wherein step (A) is continuously reacted in a first organic solvent and step (B) is continuously reacted in a second organic solvent; wherein the second organic solvent is the same as the first organic solvent of step (A) and wherein neither the first organic solvent nor the second organic solvent are THF or MTBE. Thus, Applicants maintain that the present invention is not obvious in view of Maryanoff et al., US Patent 5,387,700.

In view of the above remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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